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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,777	11/26/2003	Bruce Kevin Wagoner	4237-101	9677
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EXAMINER				
LEITH, PATRICIA A				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/723,777

Applicant(s)

WAGONER, BRUCE KEVIN

Examiner

Patricia Leith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Claims 49-62 are pending in the application and were examined on their merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly recited claims state the following limitations which cannot be found explicitly or implicitly in the original Disclosure as filed:

Claim 49:

'from 20% to 50% of urea'

'from 2% to 15% of sunflower oil'

'0.5% to 10% of shea butter'

'wherein urea and water in combination constitute a major portion of the composition'

Claim 50:

'urea in the composition is from about 20 to about 41%'

Claim 52:

'wherein the amount of sunflower oil in the composition is greater than the amount of shea butter'

Claim 53:

'from 1% to 4% of soybean sterol'

Claim 55:

'wherein the amount of urea in the composition is from 20% to 50%'

Claim 56:

'wherein the amount of sunflower oil in the composition is from 2% to 15%'

Claim 57:

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'wherein the amount of shea butter in the composition is from 0.5% to 10% by weight'

Claim 58:

'wherein urea and water in combination constitute a major portion of the composition'

Claim 59:

'urea in the composition is from about 20 to about 41%'

Claim 61:

'the amount of sunflower oil in the composition is greater than the amount of shea butter'

Claim 62:

'from 1% to 4% of soybean sterol'

Thus, these statements constitute New Matter. Applicant is asked to either point out in the original disclosure where these limitations can be found or to delete the New matter in order to overcome this rejection. Because all claims depend either directly or indirectly from a claim which recites new matter, all of the pending claims are properly rejected under this statute.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 49-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huard et al. (US 6,485,733 B1) in view of Quan et al. (US 6,180,133 B1) in view of Durr et al. (US 5,997,889) in view of Hill et al. (US 4,233,295) and in view of McNulty et al. (US 2005/0048105 A1) in view of Nagal (1977).

This rejection is reiterated from the previous Office action as it is pertinent to new claims 49-62.

Huard et al. (US 6,485,733 B1) disclosed that the ingredients of Vaseline[™] Intensive Care Extra Strength Lotion included, *inter alia*, sunflower seed oil, soya sterol, glyceryl stearate, stearic acid, triethanolamine, glycerine, water, lecithin, tocopherol acetate, retinyl palmitate, disodium EDTA and urea (see col. 18, lines 51-63).

It is noted that *Helianthus annuus* is the botanical name for sunflower.

Huard et al. did not specifically teach the incorporation of shea butter, ammonium lactate, butylated hydroxytoluene or sodium polyacrylate into the VaselineTM composition. Huard et al. also did not specifically teach the omission of parabens from the VaselineTM composition.

Quan et al. (US 6,180,133 B1) teaches that studies indicated that addition of ammonium lactate to lotions had proven moisturizing activity (col. 3, line 64- col.4, line 17).

Durr et al. (US 5,997,889) disclosed that shea butter may be added to a lotion to improve its moisturizing ability (see Abstract for example).

Hill et al. (US 4,233,295) teaches that butylated hydroxytoluene, an antioxidant, is advantageous to incorporate into creams, lotions or ointments in order to preserve the active ingredients therein (see col. 6, lines 23-26).

McNulty et al. (US 2005/0048105 A1) teaches that sodium polyacrylate is a known thickening agent for creams and lotions[0069].

It is well known in the art that people suffer from paraben allergies. Nagel et al. (1977) for example, reported paraben allergies to be on the rise, indicating that about

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3% of the population had a topical paraben allergy (see p. 1594, column 1). Nagel et al. urged the indiscriminate use of parabens as preservatives “especially not in medicines frequently given to the allergic or potentially allergic patient” (see p. 1595, column 3). Here, it is clear that it *was known in the art that patients were sensitized by parabens in cosmetics and thus had an allergy to topically applied parabens*. To reiterate from the previous Final Office Action, although it is not explicitly stated in Nagel et al. to formulate cosmetics without parabens, Nagel et al.’s reference to the ‘avoidance’ of cosmetics with parabens is clearly an implicit suggestion to the sensitized patient to use products which do not contain parabens. Hence, the ordinary artisan would clearly see the advantage of formulating cosmetics such as humectants absent parabens because there was a need for such products according to the art at the time the invention was made.

One of ordinary skill in the art would have been motivated to combine ammonium lactate and shea butter into the Vaseline TM composition because they are ingredients well known to improve moisture to the skin. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for lending moisture protection to the skin or for being used to stabilize/thicken topical cosmetic lotions/creams. This rejection is based on the well established proposition of patent law

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that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

One of ordinary skill in the art would have been motivated to incorporate butylated hydroxytoluene to the Vaseline TM composition in order to preserve the active ingredients therein. It was clear from the prior art that butylated hydroxytoluene was used as an antioxidant in creams and lotions. Thus, the ordinary artisan would have had a reasonable expectation that the addition of this ingredient would have afforded the Vaseline TM lotion a longer shelf-life.

One of ordinary skill in the art would have been motivated to add sodium polyacrylate to the Vaseline TM composition, or alternatively, to substitute sodium polyacrylate for another thickener in Vaseline TM such as methylparaben because the addition of thickening agents to lotions imparts a thicker viscosity to the lotion which has a pleasant consistency and further is easy to administer to the skin and these thickening agents are considered functional equivalents as they perform the same function; thickening the lotion. The choice of thickeners is considered a matter

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of judicious selection on the part of the ordinary artisan, and no unexpected results can be found by use of sodium polyacrylate, a known cosmetic thickening agent, over thickening agents such as methylparaben which was also a well known thickening agent.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration is an art-recognized result-effective variable which would have been routinely determined and optimized in the cosmetic and pharmaceutical arts. One of ordinary skill in the art would have been motivated to have modified the proportions of ingredients in the lotion in order to enable the content of the preparation to be matched with the demands and needs of individuals which needed treatment (e.g., regular strength –vs- extra strength). Such variations in amounts of cosmetically/ pharmaceutically active ingredients is considered merely optimization of result effective variables, conventional practice in the art of pharmacology. See also, *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."

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The Supreme court has acknowledged that:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

In addition, KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20 (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>).

Applicant's arguments were fully considered, but not found persuasive.

Applicant initially argues that, in reference to claim 49:

Such composition fails to be disclosed in or to be derivable from the cited references. Huard teaches a composition wherein sunflower oil is present in greater concentration than urea, opposite to the composition of applicant's invention as claimed in claim 49. Further, Huard fails to teach or provide any derivative basis for the use of shea butter in the composition disclosed in such reference. The examiner in the rejection of the claims previously pending in the application cited Durr for teaching of shea butter, but Durr teaches an entirely different composition than is disclosed in Huard. The Durr

formulations are either devoid of water, or if water is used at all, it is added "in an amount of up to 5% by volume of the total volume of product" (column 4, lines 27-28 of Durr). Huard, by contrast, teaches a composition in which the largest concentration ingredient is water. Based on such disparate character of the respective compositions alone, one would avoid any attempted synthesis of the two references. The other references cited in the October 17, 2007 Office Action were cited for teaching of ingredients not recited in claim 49. Claim 49 and claims 50-53 dependent thereunder are therefore patentably demarcated over the cited prior art (p.5, Remarks).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, while the references do not specifically teach the amounts of constituents as Instantly claimed as was pointed out in the previous Office action, the amounts as Instantly claimed are not deemed inventive absent a demonstration of unexpected results: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."; *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969). Applicant's arguments pertaining to the amount of water in the Instantly claimed composition are not found persuasive in that the ordinary artisan would have been motivated to adjust the amount of water to provide varying consistencies of lotion products. While Applicant argues that the teachings of Durr and Huard are inapposite in that one teaches little water and the other teaches that water is in the greatest percentages in their lotion composition and thus contends that these teachings are detrimental to the outstanding rejection; on the contrary, the prior

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art thus clearly demonstrates that water is routinely adjusted in cosmetic lotion compositions.

Each of the claimed constituents was already known in the prior art as being additives in lotions; either for moisturizing purposes or for antioxidant purposes in order to preserve the lotions/creams. Thus, the Instantly claimed compositions are deemed obvious absent any unexpected result. The ordinary artisan was fully aware that each of the claimed ingredients was well known to be used in the cosmetic field in lotions. Thus, although the prior art did not specifically disclose such compositions, the claims remain obvious in light of the prior art teachings. [If]... there are [a] finite number of identified, predictable solutions, [a] person of ordinary skill in art has good reason to pursue known options within his or her technical grasp, and if this leads to anticipated success, it is likely product of ordinary skill and common sense, not innovation *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007.

Further, Applicant's arguments that because claim 54 recites a composition consisting of water, urea, EDTA, sodium PCA, stearic acid, glyceryl searate, soybean sterol, shea butter, sunflower oil, butylated hydroxytoluene and triethanolamine, that this claim is "...not disclosed or derivable from any of the cited references" (p. 5, Remarks) is respectfully not accepted. Because each individual ingredient was already known in the prior art for use in cosmetic lotions for moisturizing the skin, it is deemed that the combination of ingredients, even taking the exclusions of other ingredients into

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consideration is deemed obvious in light of the prior art references. The prior art clearly taught the use of VaselineTM product of the prior art which contained , *inter alia*, sunflower seed oil, soya sterol, glyceryl stearate, stearic acid, triethanolamine, glycerine, water, lecithin, tocopherol acetate, retinyl palmitate, disodium EDTA and urea (again, see col. 18, lines 51-63). The Instantly claimed invention is directed toward mere variations of this known product which do not impart a patentable change; i.e., a change in which an unexpected benefit would be derived from the inclusion or exclusion of particular ingredients which were found in the prior art VaselineTM product.

Accordingly, it remains deemed that the claimed invention is obvious over the prior art because the ordinary artisan would have had a reasonable expectation of success in producing the claimed compositions.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
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